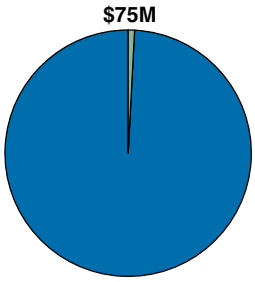
Goal 3 FY 2000 Obligations



Note: EPA FY 2000 Obligations were $8,974 million

GOAL 3: SAFE FOOD

The foods Americans eat will be free from unsafe pesticide residues. Children especially will be protected from the health threats posed by pesticide residues because they are among the most vulnerable groups in our society.

OVERVIEW

Americans have one of the safest, most abundant, and affordable food supplies in the world as a result of work done by federal, state, and local governments to manage and control the risk posed to human health by pesticide residues on food. The use of pesticides in agricultural production and food processing contributes significantly to that safety, abundance, and affordability. Ensuring that food remains safe for consumption, however, requires constant diligence on the part of pesticide producers, users, and regulatory agencies in the manufacture, labeling, storage, review, approval, and use of pesticides. EPA continues to protect the nation's food supply by reviewing all new and existing pesticides, making determinations about their safety, and denying or restricting the use of pesticides that do not meet current health or ecological standards.

The Agency addresses risk from pesticides when it registers new pesticides or reregisters older pesticides, ensuring that each pesticide meets current health and environmental protection standards and that product labeling includes complete, up-to-date, easily understandable use instructions and precautions. The reregistration program reevaluates the safety of pesticides initially registered before November 1984. To mitigate risk in cases where data indicate that a pesticide does not meet current human health and environmental standards, EPA can modify or restrict the allowable uses, including canceling use or allowing use only by a certified applicator or under supervision of a certified applicator.

In FY 2000 protection of infants, children, and other vulnerable groups remained a high priority for the Agency. EPA applies an extra tenfold safety factor (for food use pesticides) in risk assessments to account for children's special vulnerabilities, unless scientific data indicate that a different factor is warranted, and considers special dietary patterns of groups such as Native Americans, urban poor, and farm families. The Agency is continuing to update and improve its pesticide toxicity testing guidelines and other assessment tools.

In FY 2000 the Agency made further progress toward its strategic goal through a combination of regulatory, outreach, and partnership activities, including the following: (1) continuing to register new pesticides and reregister existing pesticides, emphasizing reevaluation of existing pesticides that pose the greatest health risks, and accelerating the registration of lower-risk alternatives; (2) training and educating pesticide users and applicators; and (3) encouraging the development and adoption of alternative means of pest control, including the use of nonchemical approaches and lower-risk pesticides.

FY 2000 PERFORMANCE

Reducing Agricultural Pesticide Risk

Approximately 20,000 pesticides products are currently registered or licensed for use in the United States. Pesticide products are used in or on food, around homes, businesses, schools, hospitals, and in parks. Before EPA registers a pesticide product for sale and use, the Agency evaluates test data on all of its ingredients. The test data, which include studies on the effects the product will have on humans, wildlife, fish, and plants (including endangered species), are provided by the registration applicant (known as the registrant). Depending on the type of pesticide, a registrant may be required to generate data from as many as 100 different tests in order for the Agency to determine the product's safety.

EPA is developing and evaluating improved methods to estimate human exposure to and risk from pesticides. The Agency has made considerable progress in improving its risk assessments by incorporating the latest scientific methods. For example during FY 2000 EPA published for public comment 14 draft or revised science guidelines and policy papers that describe how EPA scientists will evaluate aggregate exposure, cumulative risk, and other science policy issues when they assess pesticides under the Food Quality Protection Act (FQPA). The Agency also convened the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel six times to consult on these subjects with external scientists. Additionally the Agency consulted with stakeholders through the Tolerance Reassessment Advisory Committee and the new Committee to Advise on Reassessments and Transition, held a public technical meeting on cumulative risk, and held several public meetings on individual chemicals. Broadening stakeholder input helps the Agency gain cooperation from industry and growers in developing and implementing reduced risk agricultural practices.

Recognizing the need to develop methods that directly measure or reliably estimate these risks on a national or regional basis, EPA must currently use a variety of program activities as surrogate indicators of progress, one of which is the processing of registration applications. The Agency, in partnership with Florida State University, is working to develop a strategy for building baseline data and national environmental indicators with the ultimate goal of replacing the surrogate indicators of progress with those that reflect health effects associated with pesticides. The strategy document is expected during FY 2002.

EPA identified and solicited public comment on several new program progress indicators, including food pesticide residue data collected by the U.S. Department of Agriculture (USDA) to track reductions in the occurrence of residues of neurotoxic and carcinogenic pesticides on foods frequently eaten by children. Such indicators will help EPA to better target its limited resources to obtain the best results.

EPA completed 13 pesticide registrations for several reduced-risk pesticides. Pesticide usage data indicate that increased availability of lower-risk pesticides, combined with public demand for safe food, encourages pesticide producers and users to shift to reduced-risk alternatives.

REDUCING RISK THROUGH REGISTRATION OF REDUCED-RISK PESTICIDES

Harpin Protein. This biopesticide has the potential to be an important human health and environmental risk reduction tool. Harpin is a class of protein produced naturally. It triggers the plant's natural defense mechanism rather than directly interacting with the pest organism. For this reason, organisms are not expected to develop resistance to Harpin. Harpin is effective against certain viral diseases for which there are no other controls. It also protects against soil-borne pathogens and pests (nematodes and fungi) that have few potential controls other than methyl bromide, an ozone-depleting chemical. Approved uses include all food commodities, trees, turf, and ornamentals.

New Uses for Spinosad and Glyphosate. During FY 2000 EPA staff collaborated with USDA to design a more efficient strategy for developing and applying residue data needed to establish tolerances for the reduced-risk chemicals Spinosad and Glyphosate on more than 200 crops, including many children's foods. This effort cut data development time by 2 to 3 years for many of these uses, allowing EPA to register the additional uses of these two lower-risk pesticides in FY 2000. These changes also resulted in a direct savings of $1 million to the federally and state-funded program that developed the data. Through these streamlined registration actions, more than 150 crops may now be treated with Spinosad and approximately 250 crops may now be treated with Glyphosate instead of other, higher-risk pesticides.

As the use of reduced-risk alternatives increases, they may also become more affordable.

Because of public concern over various aspects of biotechnology (e.g., pest resistance, allergens, genetic alteration), EPA began a scientific and public review of the current registrations for certain genetically engineered corn and cotton varieties, commonly referred to as Bt corn and Bt cotton. The Agency also extended the existing registrations of Bt cotton and Bt corn plant pesticides until September 30, 2001, to allow ample time for this comprehensive review. EPA will use this comprehensive approach to ensure that decisions are based on the best available scientific analysis and that opportunity is provided for an open

dialogue with the public regarding Bt products. To ensure that all viewpoints are represented, EPA will seek input from the public from the FIFRA Science Advisory Panel, and through a review being led jointly by the Council on Environmental Quality and the White House Office of Science and Technology Policy. In addition in FY 2000 the Agency worked diligently to finalize the plant pesticide rule. EPA believes that the rule, first proposed in 1994, will clarify the status of plant-incorporated protectants under FIFRA. Plant incorporated protectants can serve as lower risk alternatives to conventional pesticides used on foods. The final rule, expected in FY 2001, will reflect careful consideration of all public comments and relevant scientific data.

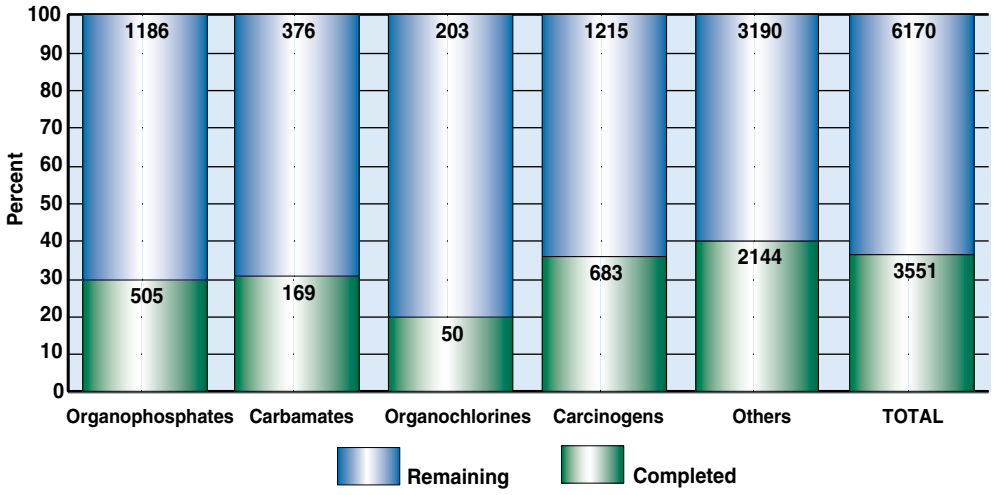
Reducing Use on Food of Pesticides Not Meeting Health Standards

Since 1988 EPA has been conducting a comprehensive review of the risks associated with pesticides initially registered before November 1, 1984. In FY 1996 FQPA added a new dimension to the pesticide reregistration program. Under FQPA, EPA evaluates pesticides to assess whether use of the pesticides in accordance with their label instructions presents "reasonable certainty of no harm." After completing a review and ensuring that the pesticide does not present human or environmental health threats, the Agency issues a Reregistration Eligibility Decision (RED). In cases where the reviews indicate that pesticides do not meet health and environmental requirements, EPA can modify the allowable uses of pesticides, including canceling use or limiting use to certified applicators. FQPA also sets stricter safety standards for pesticide residues in or on food and it requires EPA to reassess all existing tolerances within 10 years to ensure they meet the new safety standard.

In FY 2000 EPA continued to reduce human health risks (through substitution of these chemicals with safer pesticides, tolerance reassessments, and reregistration) from organophosphates and other high-risk pesticides, such as organochlorines, carcinogens, and carbamates. Because organophosphates are widely used, accounting for more than half of all food crop insecticides used in the United States, and can adversely affect the human nervous system, EPA views the reassessment of these products as a major step in risk reduction. EPA is committed to ensuring a safe and abundant food supply for Americans and recognizes that restricting use of widely used pesticides in the absence of appropriate alternatives could compromise this commitment. In FY 2000 the Agency worked in collaboration with USDA to obtain a broad range of stakeholder and public comments on its risk assessments for the organophosphate pesticides. EPA also held a number of open, public technical briefings to communicate risk concerns and obtain the views of stakeholders.

EPA made substantial progress in reviewing individual organophosphates and carbamate pesticides and characterizing their risks. The six REDs EPA completed in FY 2000 incorporate various risk-reduction measures, such as allowing use of certain products only by certified applicators, canceling pesticide products or deleting uses, limiting the amount or frequency of use, requiring additional personal protective equipment or other worker protection measures for applicators such as improving use directions and precautions, and/or employing groundwater or surface water protection.

Progress in Reassessing Pesticide Tolerances as of September 30, 2000



Status of the EPA's tolerance reassessment program, by chemical class. In total, 3, 551 tolerances (37% out of a total of 9,721) have been reassessed. Thus EPA is more than one-third complete with progress on reassessing tolerances, including high-risk chemicals such as organophosphates, carbamates, organochlorines, and carcinogens.

RISK MITIGATION ON ORGANOPHOSPHATES

Chlorpyrifos. EPA reached an agreement with pesticide manufacturers to eliminate and phase out certain uses of the organophoshate chlorpyrifos—the active ingredient in Dursban, one of the most heavily used household insecticides. This agreement will significantly reduce risk from food and residential uses, particularly to children. The agreement lowers or revokes tolerances on apples, tomatoes, and grapes; classifies new end-use products as restricted use; and reduces drinking water risk through phaseout or cancellation of most indoor/outdoor residential uses, which are major contributors to drinking water contamination.

Bensulide. EPA's review of bensulide, an organophosphate herbicide used on vegetable crops, ornamentals, and turf, found that dietary risk from residues on food was low but that aggregate risk could be significant when potential drinking water exposures through runoff from turf applications were considered. EPA worked to mitigate the risk of bensulide by prohibiting handheld application methods and treatment of large turf areas, adopting label changes, and restricting the number and timing of golf course applications.

Regulation of antimicrobial pesticides is another arena in which EPA contributes to ensuring the safety of America's food supply. During FY 2000 the Agency convened an interagency panel to review a procedure for evaluating the efficacy of consumer products intended to control disease-carrying organisms on fresh fruits and vegetables. EPA also initiated a review of procedures to evaluate the efficacy of antimicrobial agents claimed to reduce the number of disease-carrying organisms in food processing, water, and in air. Other ongoing efforts related to antimicrobial pesticides include work with stakeholder groups and scientific experts to (1) develop performance standards and efficacy tests for registering treated articles (such as cutting boards, kitchen sponges, cat litter, toothbrushes, and toys) associated with human health claims and (2) refine registration requirements and performance standards for products that claim to control human pathogens in medical waste. EPA's investments in expanded outreach and communication concerning antimicrobial pesticides have proven invaluable in providing up-to-date information to the public in instances like the FY 2000 recall of certain cleaning products found to cause respiratory symptoms in some users. The National Antimicrobial Information Network, which provides a wide variety of information about antimicrobials through a toll-free telephone number (1-800-447-6349) and the Internet (**http://www.ace.orst.edu/info/nain/**), is an example of the communication tools available.

SUMMARY OF FY 2000 PERFORMANCE

Through successful, collaborative integration of regulatory, outreach, and partnership activities, EPA made progress in ensuring that food is free from unsafe pesticide residues, especially where children are concerned. The Agency continued using the best available science in the review of new and existing pesticides. EPA also continued to expedite the registration of reduced-risk pesticides and to review the highest-risk existing pesticides first, canceling or otherwise restricting use of pesticides that do not meet the current health standards. Additionally the Agency encouraged greater public awareness about the precautions people should take in the proper preparation and handling of food. These actions played an important part in moving the Agency toward its strategic goal to improve food safety.

RESEARCH CONTRIBUTIONS

In FY 2000 EPA conducted research to develop and improve methods and models that predict, estimate, and measure health effects resulting from exposure to pesticides. Developing improved methods to detect, characterize, and quantify pesticide exposures in infants, children, and other susceptible subpopulations is an important focus of this research. The FQPA has expanded EPA's pesticide risk assessment research, particularly in the area of evaluating aggregate exposures to pesticides from multiple sources and the cumulative risk posed by multiple pesticides that share a common mechanism of toxicity. In FY 2000 research centered on providing methods and models to evaluate the risk to human health posed by food-use products. One of the most important activities was the revision of a first generation, multimedia, multipathway pesticide exposure model that identifies critical exposure pathways and factors for infants and young children. Future research will continue to focus on the development of risk assessment methods and models

for susceptible populations, but will also include a greater emphasis on the development of new exposure and effects data to address the key issues and science needs of cumulative risk.

PROGRAM EVALUATION

The General Accounting Office (GAO) assessed how EPA protects children's health and addresses their special vulnerability to pesticides in the report *Children and Pesticides: New Approach to Considering Risk Is Partly in Place* (HEHS-00-175). This investigation addressed the progress EPA has made in considering aggregate exposure and the cumulative effects of pesticides, as well as the progress made in reassessing tolerances for pesticide residues. GAO found that EPA has put in place interim procedures to address aggregate exposure and that methods for addressing cumulative risk are being developed. When complete, the methods will be implemented on a group of chemicals considered to be of potentially high risk. To address GAO concerns, EPA is giving special attention to the foods children most frequently eat (**http://www.gao.gov**).

ASSESSMENT OF IMPACTS OF FY 2000 PERFORMANCE ON FY 2001 ANNUAL PERFORMANCE PLAN

The Agency's FY 2000 target for tolerance reassessments was not met due in part to the continuing development of the cumulative risk methodology. The Agency has already done a substantial amount of work on many tolerances but cannot call the tolerances fully reassessed because of the pending development of the Agency's cumulative risk policy. Once the cumulative risk policy has been approved (expected by the end of FY 2001) and applied to the tolerance reassessment process, the Agency expects to increase the pace of tolerance reassessments. Therefore the Agency will revise its FY 2002 Annual Performance Goal (APG) for tolerance reassessment upward so that the Agency will be on track to meet the statutory requirement of 66 percent of existing tolerances reassessed by 2002. The Committee to Advise on Reassessments and Transition, which began in FY 2000, will continue to add diverse stakeholder input to EPA's decision-making process. Lessons learned from the organophosphate pesticide review process, particularly the need for better data and collaboration among stakeholders, will be applied to the evaluation of other high-risk pesticides in FY 2001. The FQPA requirement to address the cumulative risk of all pesticides sharing a common mechanism of toxicity will continue to affect EPA's tolerance assessment completions in FY 2001. In addition, the Agency is revising its 2001/2002 targets upwards for several registration outputs to better reflect process improvements made since 1997.

TABLES OF RESULTS

The following tables of results includes performance results for the two FY 2000 Congressional APGs that appear in Goal 3. In cases where the FY 2000 APG is associated with a FY 1999 APG, the table includes the FY 1999 APG below the FY 2000 APG for ease in comparing performance.

Summary FY 2000 Performance
1 Goals Met | 1 Goals Not Met | 0 Other

GOAL 3 - SAFE FOOD

FY 2000 ANNUAL PERFORMANCE GOALS AND MEASURES	FY 2000 Planned	FY 2000 Actual	FY 1999 Actual
BY 2005, THE RISK FROM AGRICULTURAL USE OF PESTICIDES WILL BE REDUCED BY 50 PERCENT FROM 1995 LEVELS.			
FY 2000 APG 19: **Decrease adverse risk from agricultural uses from 1995 levels and assure that new pesticides are safe by such actions as registering 6 new chemicals, 2,200 amendments, 600 me-toos, 200 new uses, 45 inerts, 375 special registrations, 225* tolerances and 13 reduced risk chemicals/biopesticides.**	6 2,200 600 200 45 375 225 13	6 3,069 1,106 427 95 458 452 16	7 3,586 1,022 681 109 455 351 19
(FY 1999) *Decrease adverse risk from agricultural pesticides from 1995 levels and assure new pesticides that enter the market are safe for humans and the environment.*			
Explanation: Goal met. Pending availability of improved indicators, the Agency uses the processing of registration applications as surrogate measures. In partnership with Florida State University, the Agency is refining environmental indicators for pesticide programs and is analyzing ways to measure risk posed by agricultural uses of pesticides. It is likely that the risk will be inferred by examining usage levels of safer "reduced-risk" pesticides, using 1995 (pre-Food Quality Protection Act) as a baseline. Revised perfomance indicator/measure is expected in FY 2002. *The APG for FY 2000 contained in the FY 2001 Congressional Justification erroneously included 105 tolerances, yet indicated 225 tolerances as the planned performance measure target for 2000. The correct number of tolerances for the 2000 APG is 225. In this report, EPA is referencing 225 tolerances, as written in the FY 2001 Congressional Justification as a performance measure target for 2000.			
Data Source: The Pesticide Regulatory Action Tracking System is designed to collect and track information submitted by the regulated industry to support a pesticide registration application. The Tolerance Index System (TIS) contains information on current tolerances, crop residues by crop and crop group for food and feed use.			
Data Quality: EPA conducts internal senior management reviews of data contained in pesticide tracking systems. EPA is developing two databases: (1) Office of Pesticide Program Information Network (OPPIN) to consolidate pesticide data into one system and (2) the National Pesticide Residue Database (NPRD), in conjunction with the Food and Drug Administration, U.S. Department of Agriculture, and the states of California and Florida, to automate validation of data submissions. The NPRD is being created in response to a recommendation by the National Academy of Science (NAS) Report *Pesticides in the Diets of Infants and Children, 1993.* The report provided the findings by NAS National Research Council Committee on its examination of the adequacy of present risk assessment methods and policies and toxicologic issues of most concern to children. One of the findings was that there was no comprehensive data source on pesticide residue levels in the major foods consumed by infants and children. The purpose of the database is to have a single national repository of pesticide residue monitoring data with consistent/standardized reporting of data.			

FY 2000 ANNUAL PERFORMANCE GOALS AND MEASURES		FY 2000		FY 1999
		Planned	Actual	Actual
BY 2005, USE ON FOOD OF CURRENT PESTICIDES THAT DO NOT MEET THE NEW STATUTORY STANDARD OF "REASONABLE CERTAINTY OF NO HARM" WILL BE SUBSTANTIALLY ELIMINATED.				
FY 2000 APG 20:	**EPA will reassess 20% of the existing 9,721 tolerances to ensure that they meet the statutory standard of "reasonable certainty of no harm."**	**1,250**	**121***	
(FY 1999)	*Under pesticide reregistration, EPA will reassess 19% (or 1,850) of the existing 9,700 tolerances (cumulative 33%) for pesticides food uses to meet the new statutory standards of "reasonable certainty of no harm."*			**1,445**
Explanation:	Goal not met. As of September 2000, the Agency had completed 3,430 (or 35%) of the statutorily mandated 9,721 tolerances. Despite the FY 2000 performance, the Agency expects to meet the Food Quality Protection Act (FQPA) August 3, 2002 statutory deadline of 66% of tolerances reassessed (6,415) and 100% assessed by August 2006. Although the actual results are less than the targets, the Agency has already done a substantial amount of work on many tolerances. However, the Agency cannot call the tolerances fully reassessed because of the pending development of the Agency's cumulative risk policy. *In FY 2000 EPA targeted the organophosphate pesicides (OPs) for tolerance reassessment. Because the OPs share a common mechanism of toxicity, a cumulative risk assessment across all of the OPs is required before the reassessment of their tolerances is completed. This extra stage of cumulative assessment was not needed for the tolerances reassessed in FY 1999. The cumulative assessment requires that EPA establish a cumulative risk policy, which has taken the Agency longer than first anticipated. EPA now expects to issue that policy by the end of FY 2001. Following that the Agency will be able to complete the reassessment of all of the OP tolerances, producing a surge of reassessments completed in FY 2002. EPA is on schedule to meet the statutory deadline of 66% of all tolerances reassessed by August 3, 2002.			
Data Source:	Same as FY 2000 APG 19. Tolerance Reassessment Tracking System contains records on all 9,721 tolerances subject to reassessment from all sources. Data is extracted from the TIS and contains the numbers of total tolerances reassessed and the results of the reassessments (i.e., number of tolerance levels raised, revoked, or decreased).			
Data Quality:	Same as FY 2000 APG 19.			